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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,571	07/13/2000	Paul Harris	5951.010-US	4949

25907 7590 07/14/2003  
NOVOZYMES BIOTECH, INC.  
1445 DREW AVE  
DAVIS, CA 95616

EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

18

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/615,571

Applicant(s)

Harris et al.

Examiner

Scott D. Priebe, Ph.D.

Art Unit

1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 6, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Feb 3, 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see next page

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 125-128

Claim(s) objected to: 105-107, 112, and 116

Claim(s) rejected: 100-104, 108-111, 113-115, and 117-124

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

SCOTT D. PRIEBE, PH.D.  
PRIMARY EXAMINER  
ART UNIT 1632

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**Advisory Action****Item 5:**

With respect to section I of the arguments, Appellant points out that the phospholipase B encoded by the claimed nucleic acid sequence is a new class of phospholipase B. It is unclear how this aids Appellant's cause here. Since the single disclosed species represents the sole disclosed species of a potentially new genus, one of skill in the art cannot rely upon previously known phospholipase B enzymes in order to envision changes which can be made to the disclosed species which would not eliminate phospholipase B activity. The argument concerning inadequate patent protection has been addressed previously. Appellant argues that the limitations with respect to hybridization with and per cent identity to SEQ ID NO: 1 dictates structural similarity between the claimed genus and the single disclosed nucleic acids. However, the claims further require that the claimed nucleic acid sequence encode a phospholipase B. Appellant has provided no evidence to support a contention that structural similarity between nucleic acids in any way determines whether the polypeptides they encode (if any) share a specific function. The grounds of rejection set forth in the Office action of 12/17/01 provided extensive discussion of why structural similarity between nucleic acids is not predictive of protein function.

With respect to both sections I and II of the arguments, Appellant argues that the specification teaches how to use the disclosed species in order to isolate other species of the claimed genus by hybridization from nucleic acids of other organisms. With respect to the written description rejection, this argument is not relevant. Appellant is again reminded that an

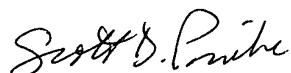
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adequate written description of a nucleic acid sequence requires more than a statement that it is the invention and disclosure of a "potential" method for isolating it, *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997). With respect to the enablement rejection, the claimed nucleic acid sequence is not limited to nucleic acid sequences which can be isolated from other organisms, and the specification provides no guidance as to what other organisms would provide a source for nucleic acid sequences embraced by the claims.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Primary Examiner  
Technology Center 1600  
Art Unit 1632